K090878

APR - 3 2009

6. 510(k) Summary

CONFIDENTIAL

6.1. Submitter Information

510(k) Submitter: Terumo Cardiovascular Systems Corporation
6200 Jackson Road,
Ann Arbor, MI 48103

Primary Contact Name: Christina Thomas,
Manager, Regulatory Affairs
Tel: 1(800)262-3304, Extension 6278
Fax: (734)741-6030

Secondary Contact Name: Steven Arick,
Director, Regulatory Affairs
Tel: 1(800)262-3304, Extension 6292
Fax: (734)741-6030

Date Prepared: March 30, 2009

6.2. Device Names, Predicate Device Names, and Predicate Device 510(k) Numbers:

Name of the Unmodified Device	510(k) Number of Sponsor's Unmodified Device	Clearance date	Name of the Modified Device
TenderFlow™ Pediatric Venous Return Cannula	K062597	1994-02-22	X-coated TenderFlow™ Pediatric Venous Return Cannula

These devices are substantially equivalent in intended use, materials, design, technology, principles of operation, and performance.

6.3. Statement of Identical Intended Use(s)/Indications:

TCVS asserts that the intended use(s)/indications for the X-coated TenderFlow™ Pediatric Venous Return Cannula are the same intended use(s)/indications that currently exist for the unmodified TenderFlow™ Pediatric Venous Return Cannula.

These devices are indicated for up to 6 hours of use.

6.4. Principles of Operation and Technology:

The X-coated pediatric venous return cannulae discussed in this submission are used in open heart surgery.

During open heart surgery blood is drained into a venous cannula just upstream of the heart, at the superior / inferior vena cava and right atrium. The cannula is connected to tubing that routes the blood to a heart / lung machine where the blood is pumped and oxygenated. The blood then continues through this perfusion circuit back to the outlet side of the heart (the patient's aorta), where the blood re-enters the patient's circulatory system via the ascending aorta through an arterial cannulae. Platelets adhesion is reduced while blood travels through this circulatory path on the surface covered with X-coat polymer.

6.5. Design and Materials:

The design of cannulae and catheters is such that they meet their stated intended use, and provide an acceptable level of performance and safety to the patients. Except for the X-coat application, the design and material of the X-coated cannulae will remain the same as the unmodified cannulae. The X-coat application does not affect the cannulae design.

Venous cannulae contained in this submission are structured as straight, or slightly curved, flexible tubes which are inserted into the heart to circulate blood. Depending on the location of cannulation, size, and clinicians' preference, there is a range of design variations. These features include, but are not limited, wire reinforcement, various stylets used to help guide the cannula, tip formation (conical vs. angled), number of drainage baskets (two stage), luers, and connectors.

The generic materials for these cannulae will remain the same.

6.6. Performance Evaluations:

The performance of the X-coated Cannulae will remain the same as the unmodified cannulae. The X-coat application does not affect the functional cannulae performance. The X-coat application reduces the platelet adhesion.

The following performance evaluations of the cannulae were conducted to demonstrate its equivalence to the uncoated cannulae.

- Hemolysis
- Bond Strength
    - Leak testing
    - Pull strength testing
    - Flex testing
- Accelerated aging / Shelf life test

6.7. Substantial Equivalence Comparison:

6.7.1. Intended Use:

The intended use of the modified device will remain the same as the predicate device.

6.7.2. Principles of Operation and Technology:

The principle of operation & technology used in the modified device will remain the same as the predicate device.

6.7.3. Design and Materials:

The design and materials, except for the X-coat application, will remain the same.

6.7.4. Substantial Equivalence Summary:

In summary, the X-coated cannulae and the uncoated cannulae are substantially equivalent in intended use, principles of operation and technology, design, and performance. Any noted differences between the devices do not raise new issues of safety and effectiveness.

6.8. Additional Safety Information

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.
- Post-sterilization release for use will be determined in consideration of maximum Ethylene Oxide, Ethylene Chlorohydrin and Ethylene Glycol (as appropriate) residue limits and maximum levels of patient exposure in accordance with EN ISO 10993-7 and AAMI TIR-19.
- Biocompatibility studies were conducted using the same materials or combination of materials for predicate devices as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993: 2003, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.
- Terumo has conducted material characterization studies – including physio-chemical profiles of aged and non-aged devices to demonstrate stability of the materials, and found the materials to be stable over the expiry of the product.

6.9. Conclusion

In summary, the X-coated pediatric venous return cannulae are substantially equivalent in intended use, principles of operation and technology, design and performance to the uncoated pediatric venous return cannulae.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Terumo Cardiovascular Systems
c/o Ms. Christina Thomas
Manager, Regulatory Affairs
6200 Jackson Road
Ann Arbor, MI 48103

APR - 3 2009

Re: K090878
X-coated TenderFlow™ Pediatric Venous Return Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing Vascular Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DWF
Dated: March 30, 2009
Received: March 31, 2009

Dear Ms. Thomas:

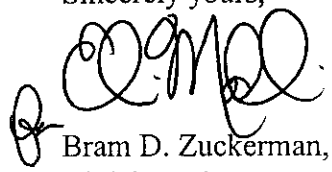
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: X-coated TenderFlow™ Pediatric Venous Return Cannula

Indications For Use:

The X-coating is intended to reduce the adhesion of platelets to the blood contacting surfaces of the device during cardiopulmonary bypass procedures.

The X-coated TenderFlow™ Pediatric Venous Return Cannula is indicated for use in dual cannulation of the superior and inferior vena cava and single cannulation of the right atrium during cardiopulmonary bypass surgery.

These devices are indicated for up to 6 hours of use.

Christina Thomas
Manager, Regulatory Affairs
Terumo Cardiovascular Systems

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K010878

CONFIDENTIAL